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EXAMINER	
AUGHENBAUGH, WALTER	
ART UNIT	PAPER NUMBER
1794	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/669,059	SCHOENLE ET AL.	
	Examiner	Art Unit	
	WALTER B. AUGHENBAUGH	1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 August 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *74,77-79,84,87,88,130,132,140,142,144-150 and 152* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *74,77-79,84,87,88,130,132,140,142,144-150 and 152* is/are rejected.

7)☒ Claim(s) *150 and 152* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgement of Applicant's Amendments

1. The Amendment filed August 27, 2009 has been received and considered by Examiner. Applicant cancelled claims 131 and 133.

NEW OBJECTION

Claim Objections

2. Claims 150 and 152 are objected to because of the following informalities: claims 150 and 152 recite "as". It appears that "as" should be "has". See, for example, claims 140 and 142. Appropriate correction is required.

WITHDRAWN OBJECTIONS

3. The objection to the specification made of record in the previous Office Action mailed May 27, 2009 has been withdrawn due to Applicant's arguments in the Amendment filed August 27, 2009.

4. The objection to claim 149 made of record in the previous Office Action mailed May 27, 2009 has been withdrawn due to Applicant's arguments in the Amendment filed August 27, 2009.

WITHDRAWN REJECTIONS

5. The 35 U.S.C. 112, first paragraph, rejection of claim 149 made of record in the previous Office Action mailed May 27, 2009 has been withdrawn due to Applicant's arguments in the Amendment filed August 27, 2009.

6. The 35 U.S.C. 112, second paragraph, rejection of claims 131 and 133 made of record in the previous Office Action mailed May 27, 2009 has been withdrawn due to Applicant's cancellation of claims 131 and 133.

7. The 35 U.S.C. 112, second paragraph, rejection of claim 149 made of record in the previous Office Action mailed May 27, 2009 has been withdrawn due to Applicant's arguments in the Amendment filed August 27, 2009.

REPEATED REJECTION

Claim Rejections - 35 USC § 103

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

9. Claims 74, 77-79, 84, 87, 88, 130, 132, 140, 142, 144-150 and 152 are rejected under 35 U.S.C. 103(a) as being unpatentable over Callol et al. (USPN 6,709,440).

In regard to independent claim 74, and claims 140 and 150, Callol et al. teach a balloon catheter that corresponds to the balloon catheter as claimed (see, for example, col. 5, lines 27-56). Callol et al. teach that the shaft includes a region that comprises a polyamide having a tensile strength of at least 15,000 psi (col. 29, lines 12-30).

Callol et al. fail to explicitly teach that the tensile strength of the polyamide is at least about 21,000 psi, and the recited thickness of the wall of the shaft.

However, since Callol et al. teach that the polyamide of the shaft has a tensile strength of at least 15,000 psi (col. 29, lines 12-30), and that the outer tubular member (which is a component of the shaft, see for example, col. 24, lines 13-31) is formed of a relatively high

strength material (col. 29, lines 1-6). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have varied the tensile strength of the polyamide used for the material of the shaft in order to achieve the desired degree of strength of the shaft wall depending on the particular desired end result depending on the desired end use, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art in the absence of unexpected results. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). MPEP 2144.05 II.B.

Furthermore, since Callol et al. teach that the outer tubular member (which is a component of the shaft, see for example, col. 24, lines 13-31) is formed of a relatively high strength material (col. 29, lines 1-6), it would have been obvious to one of ordinary skill in the art at the time the invention was made to have varied the thickness of the wall of the shaft of Callol et al. in order to achieve the desired degree of strength of the shaft wall depending on the particular desired end result depending on the desired end use, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art in the absence of unexpected results. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). MPEP 2144.05 II.B.

In regard to claim 77, Callol et al. teach the catheter as discusse above. Callol et al. teach that the tubular members may comprise one or more layers (col. 23, line 66-col. 24, line 13). While Callol et al. do not specifically teach that the different layers have different flexibilities, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used different materials for the different layers in order to achieve the optimal combination of properties obtainable from the different materials of the different layers. Different materials

have different flexibilities, so the layers that would result from the catheter having a multilayered shaft having different materials would have different flexibilities.

In regard to claim 78, Callol et al. teach the catheter as discusse above.

Callol et al. fail to explicitly teach that the tensile strength of the polyamide is at least about 22,500.

However, since Callol et al. teach that the polyamide of the shaft has a tensile strength of at least 15,000 psi (col. 29, lines 12-30), and that the outer tubular member (which is a component of the shaft, see for example, col. 24, lines 13-31) is formed of a relatively high strength material (col. 29, lines 1-6). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have varied the tensile strength of the polyamide used for the material of the shaft in order to achieve the desired degree of strength of the shaft wall depending on the particular desired end result depending on the desired end use, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art in the absence of unexpected results. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). MPEP 2144.05 II.B.

In regard to claim 130, Callol et al. teach that a polyamide copolymer is a suitable polyamide for the material of the shaft (col. 29, lines 16-24). While Callol et al. fail to explicitly teach that the tensile strength of the polyamide copolymer is at least about 21,000, Callol et al. teach that the polyamide of the shaft has a tensile strength of at least 15,000 psi (col. 29, lines 12-30), and that the outer tubular member (which is a component of the shaft, see for example, col. 24, lines 13-31) is formed of a relatively high strength material (col. 29, lines 1-6). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to

have varied the tensile strength of the polyamide copolymer used for the material of the shaft in order to achieve the desired degree of strength of the shaft wall depending on the particular desired end result depending on the desired end use, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art in the absence of unexpected results. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). MPEP 2144.05 II.B.

In regard to claims 144-149, the structural limitations that are positively recited in claims 144-149 fall within the scope of the teachings of Callol et al. Limitations such as "the distal inner lumen is a guide wire lumen" (claim 145) are intended use phrases that have not been given patentable weight, since it has been held that a recitation with respect to the manner in which a claimed article is intended to be employed does not differentiate the claimed article from a prior art article satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQd 1647 (1987).

In regard to independent claim 84, and claims 142 and 152, Callol et al. teach a balloon catheter that corresponds to the balloon catheter as claimed (see, for example, col. 5, lines 27-56). Callol et al. teach that the shaft includes a region that comprises a polyamide having a tensile strength of at least 15,000 psi (col. 29, lines 12-30).

Callol et al. fail to explicitly teach that the hoop stress of the polyamide is at least about 3300 psi, and the recited thickness of the wall of the shaft.

However, Callol et al. teach that the polyamide of the shaft has a tensile strength of at least 15,000 psi (col. 29, lines 12-30), and that the outer tubular member (which is a component of the shaft, see for example, col. 24, lines 13-31) is formed of a relatively high strength material

(col. 29, lines 1-6). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have selected a polyamide having a certain hoop stress in order to achieve the desired degree of strength of the shaft wall depending on the particular desired end result depending on the desired end use, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art in the absence of unexpected results. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). MPEP 2144.05 II.B.

Furthermore, since Callol et al. teach that the outer tubular member (which is a component of the shaft, see for example, col. 24, lines 13-31) is formed of a relatively high strength material (col. 29, lines 1-6), it would have been obvious to one of ordinary skill in the art at the time the invention was made to have varied the thickness of the wall of the shaft of Callol et al. in order to achieve the desired degree of strength of the shaft wall depending on the particular desired end result depending on the desired end use, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art in the absence of unexpected results. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). MPEP 2144.05 II.B.

In regard to claim 87, Callol et al. teach the catheter as discusse above. Callol et al. teach that the tubular members may comprise one or more layers (col. 23, line 66-col. 24, line 13). While Callol et al. do not specifically teach that the different layers have different flexibilities, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used different materials for the different layers in order to achieve the optimal combination of properties obtainable from the different materials of the different layers. Different materials

have different flexibilities, so the layers that would result from the catheter having a multilayered shaft having different materials would have different flexibilities.

In regard to claim 78, Callol et al. teach the catheter as discusse above.

Callol et al. fail to explicitly teach that the hoop stress of the polyamide is at least about 3500.

However, Callol et al. teach that the polyamide of the shaft has a tensile strength of at least 15,000 psi (col. 29, lines 12-30), and that the outer tubular member (which is a component of the shaft, see for example, col. 24, lines 13-31) is formed of a relatively high strength material (col. 29, lines 1-6). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have selected a polyamide having a certain hoop stress in order to achieve the desired degree of strength of the shaft wall depending on the particular desired end result depending on the desired end use, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art in the absence of unexpected results. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). MPEP 2144.05 II.B.

In regard to claim 132, Callol et al. teach that a polyamide copolymer is a suitable polyamide for the material of the shaft (col. 29, lines 16-24). While Callol et al. fail to explicitly teach that the hoop stress of the polyamide copolymer is at least about 3300, Callol et al. teach that the polyamide of the shaft has a tensile strength of at least 15,000 psi (col. 29, lines 12-30), and that the outer tubular member (which is a component of the shaft, see for example, col. 24, lines 13-31) is formed of a relatively high strength material (col. 29, lines 1-6). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have selected a polyamide copolymer having a certain hoop stress in order to achieve the desired

degree of strength of the shaft wall depending on the particular desired end result depending on the desired end use, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art in the absence of unexpected results. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). MPEP 2144.05 II.B.

Response to Arguments

10. Applicant's arguments presented on pages 8-10 of the Amendment regarding the 35 U.S.C. 103 rejection of the claims over Callol et al. (USPN 6,709,440) have been fully considered but are not persuasive.

Claims 74 and 84 are the sole independent claims.

In regard to both claims 74 and 84, Applicant's arguments do not acknowledge or address the portion of the rejection that is copied below:

> Furthermore, since Callol et al. teach that the outer tubular member (which is a component of the shaft, see for example, col. 24, lines 13-31) is formed of a relatively high strength material (col. 29, lines 1-6), it would have been obvious to one of ordinary skill in the art at the time the invention was made to have varied the thickness of the wall of the shaft of Callol et al. in order to achieve the desired degree of strength of the shaft wall depending on the particular desired end result depending on the desired end use, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art in the absence of unexpected results. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). MPEP 2144.05 II.B.

Pages 5-6 of Office Action mailed May 27, 2009 (in regard to claim 74) (similar text on pages 8-9 of Office Action mailed May 27, 2009 in regard to independent claim 84). Therefore, Applicant has not offered any rebuttal against this basis of rejection, which proposes that it would have been obvious to one of ordinary skill in the art at the time the invention was made to have varied the thickness of the shaft of Callol et al. in order to achieve the desired degree of

strength of the shaft wall. Also note that the discussion at col. 18, lines 42-55 of Callol et al. confirms that an increase in thickness of a polymeric material increases its strength (and vice versa: the less thick the polymeric material, the more flexible it is). Col. 18, lines 42-55 of Callol et al. also confirms that an increase in thickness of a polymeric material increases its radial (hoop) strength (col. 18, line 45) (and vice versa).

Applicant acknowledges that Callol et al. teach a tensile strength of at least 15,000 psi, but appears to argue that a disclosure of a range of at least 15,000 psi does not teach a range of at least 21,000 psi. However, since the range of at least 21,000 falls within the range of at least 15,000 psi, one of ordinary skill in the art would have reasonably expected "at least 21,000" to be taught or suggested by "at least 15,000". Applicant states that 50,000,000 psi does not fall within the "at least 15,000" range for polyamides, but 50,000,000 psi is far from 21,000 psi.

In the last full paragraph of page 8, Applicant argues that tensile strength is not a variable like "ratios (In re Antoine), percentages (In re Boesch), temperatures, dimensions and so forth", but wall thickness is a variable. As confirmed by col. 18, lines 42-55 of Callol et al., variation in the thickness of a polymeric material results in variation of strength of the polymeric material (as stated above). As stated above, Applicant has not offered any rebuttal against the basis of rejection of record which proposes that it would have been obvious to one of ordinary skill in the art at the time the invention was made to have varied the thickness of the shaft (which is a variable in line with Applicant's arguments in the last full paragraph of page 8 [for example, thickness is a dimension]) of Callol et al. in order to achieve the desired degree of strength of the shaft wall.

Conclusion

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Walter B. Aughenbaugh whose telephone number is (571) 272-1488. The examiner can normally be reached on Monday-Thursday from 9:00am to 7:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rena Dye, can be reached on (571) 272-3186. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Walter B Aughenbaugh /
Examiner, Art Unit 1794

11/03/09

/Rena L. Dye/
Supervisory Patent Examiner, Art Unit 1794